

**TCT-733****Acute Hemodynamic Effects of Percutaneous Transluminal Caval Flow Intermittent Restriction with Balloon, in Ischemic and Non Ischemic Heart Failure Patients**

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**BACKGROUND** Up to the present, preload reduction in congestive heart failure (CHF) patients is performed with high potency diuretics. Last year, we reported in TCT/ACC 2014 the hemodynamic changes of the first CHF case in humans, using Percutaneous Transluminal Caval flow Restriction (PTCR) procedure achieved with caval counterpulsation balloon (CCPB). This innovative method reduced preload in CHF. In this study we are reporting the results of the 6 consecutive patients with CHF, treated with intermittent preload reduction of caval flow with CCPB, guided by the respiratory phases.

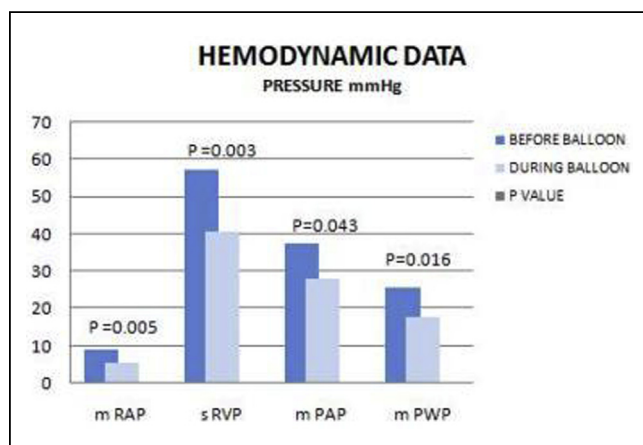
**METHODS** 6 patients with CHF who met our protocol criteria, were evaluated. 4 were ischemic, and 2 non ischemic. The mean age was  $58 \pm 9$ . 4 male mean age  $55 \pm 6$  years, and 2 female mean age  $63 \pm 4$ . We performed baseline Doppler echocardiography, coronary angiography and right heart catheterization. Subsequently caval flow restriction was started, through the right femoral vein, catheter balloon was introduced in the femoral vein and echo guided, placed just before hepatic vein drainage. The balloon was inflated according to previous calculations, to cover Inferior Vena Cava (IVC) remaining area completing 100% (total occlusion), and 70% during expiration (sub-occlusion), assuming 30% inspiratory collapse, resulting intermittent flow. The balloon was kept inflated for 30 minutes, right catheterization and echocardiography were repeated during inflated balloon. The balloon was removed and deflated.

**RESULTS** Table 1. Hemodynamic Variables. Graphic 1. Hemodynamic Data.

Table 1

Hemodynamic Variables		Before Balloon	During Balloon	% of Change	p Value
1	Mean RAP mmHg	9.00	5.67	-37%	<b>0.005</b>
2	s RVP mmHg	57.17	40.33	-30%	<b>0.003</b>
3	Mean PAP mmHg	37.50	28.00	-26%	<b>0.043</b>
4	Mean PWP (mmHg)	25.50	17.50	-32%	<b>0.016</b>
5	CARDIAC OUTPUT l/ min	4.09	4.50	10%	<b>0.157</b>

Statistical significance was defined as  $P < 0.05$



**CONCLUSIONS** We are reporting our hemodynamic and echocardiographic experience in 6 patients with CHF treated with intermittent reduction of preload with CCPB. Hemodynamic and echocardiographic changes obtained in these patients, suggest, that this innovative approach can play a role in the treatment of CHF patients.

**CATEGORIES OTHER:** Pre-Clinical/First In-Human Studies

**KEYWORDS** Balloon, Device therapy, Innovation

**TCT-734****Heart Failure Functional Classification Following Transcatheter versus Surgical Aortic Valve Replacement: a Meta-Analysis of Three Randomized Controlled Trials**

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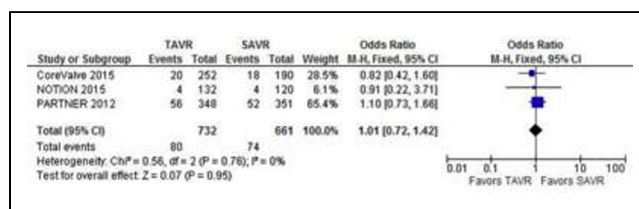
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**BACKGROUND** The decision to intervene in severe aortic stenosis is highly dependent on the patient's symptoms and functional capacity. Approximately 80% of patients with severe symptomatic aortic stenosis who are high-risk operable candidates for surgical aortic valve replacement (SAVR) are in functional class III or IV upon enrollment in clinical trials. Among patients who are eligible for both procedures, a recently published randomized controlled trial (RCT) found that transcatheter aortic valve replacement (TAVR) is associated with a higher New York Heart Association (NYHA) functional class at 1-year as compared to SAVR. This finding was not observed in other RCTs. We aimed to perform a meta-analysis of RCTs comparing heart failure functional classification following TAVR vs. SAVR.

**METHODS** Pubmed, EMBASE, Cochrane Central, and conference abstracts were searched for RCTs that (1) directly compared TAVR to SAVR in patients with severe symptomatic aortic valve stenosis and (2) reported NYHA functional class outcomes in (3) a follow-up period greater than 1 year. In studies with overlapping populations, only the one with the largest sample size was included. Odds-ratios were computed using random or fixed-effects models. Heterogeneity was examined with I<sup>2</sup> statistics. Review Manager 5.1 was used for meta-analysis statistics.

**RESULTS** Three RCTs with a total of 1,393 patients were included, of whom 732 (52.5%) underwent TAVR. In a follow-up that ranged from 1 to 2 years, no significant difference was observed between treatment groups with regards to NYHA functional class IV (OR 0.55; 95% CI 0.23-1.32; p=0.18), functional class III or IV (OR 1.01; 95% CI 0.72-1.42; p=0.95), and functional class I (OR 0.86; 95% CI 0.55-1.36; p=0.53).



**CONCLUSIONS** Our meta-analysis suggests that in patients with severe symptomatic aortic stenosis who are eligible for surgery, TAVR is as effective as SAVR for improvement in heart failure symptoms in a 1 to 2-year follow-up. Ongoing trials will provide insights as to long-term results.

**CATEGORIES STRUCTURAL:** Heart Failure

**KEYWORDS** Heart failure, Surgical aortic valve replacement, TAVR